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EXAMINER

MARTINELLI, JAMES

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1631

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/021,323
Filing Date: December 12, 2001
Appellant(s): DEIKMAN ET AL.

Thomas E. Holsten
For Appellant

EXAMINER'S ANSWER

This is in response to the brief on appeal filed July 13, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because appellants assert (brief filed July 13, 2004, page 3, section 7) that the separate patentability for claims 1-2, 4-10, 11-15, and 16-17 is addressed in Section 8.B(4) of the brief. However, only an argument for separate patentability of claims 1, 2, and 11-17 as compared with claims 4-10 is seen in the entirety of section 8 of the brief. Accordingly, the argument in this examiner's answer will be

Art Unit: 1631

directed to the separateness of claims 1, 2, and 11-17 as one group and claims 4-10 as a second group in connection with the rejections under 35 USC § 101 and 35 USC § 112, first paragraph.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims.

Rejection of claims 4 and 5 under 35 USC § 112, second paragraph

Claims 4 and 5 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite. The recitation of structural nucleic acid molecule (claims 4 and 5) is vague and indefinite. The application confuses the term "structural nucleic acid" with the term of art "structural gene" (*e.g.*, see *Dictionary of Biochemistry and Molecular Biology*, Second Edition, Stenesh, 1989, John Wiley & sons, New York, page 454). Appellants' argument (brief filed July 13, 2004, pages 13-14) is not convincing. Appellants do not address the definition in Stenesh. Although appellants are allowed to be their own lexicographers, no harm is seen (nor have appellants pointed out any harm) in using the accepted term in place of an invented term that is open to interpretation. It was noted in the Final Office action (mailed February 13, 2004, page 2) that the substitution of "a nucleic acid sequence

Art Unit: 1631

that encodes an amino acid sequence" for "structural nucleic acid molecule" would be sufficient to overcome this rejection.

Rejection of claims 1, 2, and 4-17 under 35 USC § 101 for lack of patentable utility

Claims 1, 2, and 4-17 are rejected under 35 USC § 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for either SEQ ID NO: 13 or a polypeptide encoded by SEQ ID NO: 13. Likewise, no specific, substantial, and credible utility would be readily apparent to one of skill in the art from the disclosure and what was known in the art as of the effective filing date of the instant claims. Appellants' arguments (brief filed July 13, 2004, pages 3-12) amount to a series of assertions about SEQ ID NO: 13. They are:

- (a) The claimed sequence has use for identifying the presence or absence of genetic polymorphisms (*e.g.*, brief filed July 13, 2004, page 3, line 23; page 5, line 18; page 6, line 10; page 7, lines 1-2; page 7, lines 10-11; page 7, line 20; and page 10, lines 20-23).
- (b) The claimed sequence has use as a genetic marker (*e.g.*, brief filed July 13, 2004, page 5, line 17).
- (c) The claimed nucleic acid has use as a hybridization probe for monitoring expression (*e.g.*, brief filed July 13, 2004 page 5, lines 18-19).
- (d) The claimed nucleic acid has utility in the measurement of levels of mRNA in a sample (*e.g.*, brief filed July 13, 2004, page 6, line 6).
- (e) The claimed nucleic acid has use as molecular markers (*e.g.*, brief filed July 13, 2004, page 6, lines 6-7).
- (f) The claimed nucleic acid has use as probes for other molecules (*e.g.*, brief filed July 13, 2004, page 8, lines 4-5).
- (g) The claimed nucleic acid has use as a source of primers (*e.g.*, brief filed July 13, 2004, page 8, line 5).

Art Unit: 1631

- (h) The claimed nucleic acid has use in the isolation of promoters (*e.g.*, brief filed July 13, 2004, page 8, lines 17-19 which states "a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule."). See also page 9, lines 2-3.
- (i) The claimed nucleic acid may be used as a starting point for chromosome walking or a chromosome landing (*e.g.*, brief filed July 13, 2004, page 8, lines 19-20 and page 9, lines 18-20).
- (j) The claimed nucleic acid may be used to identify markers (*e.g.*, brief filed July 13, 2004, page 9, line 2).

Appellants' assertions and arguments are not convincing because there is no disclosure of a function for any sequence encoded by SEQ ID NO: 13. Nor is there any disclosure of any particular genetic location for SEQ ID NO: 13. Thus, the assertions in the brief do not show a specific, substantial, and credible utility for SEQ ID NO: 13. For example, in the absence of a disclosure of a function for any polypeptide that may be encoded by SEQ ID NO: 13, assertions (a)-(g) and (j) above do not meet the requirement for a specific utility or a substantial utility (*Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966)) for the claimed invention in its current form (*i.e.* as of the effective filing date). The measurements of polymorphisms or levels of expression have no meaning in the vacuum of ignorance of the function of the sequence. Likewise, the preparation of probes for a sequence about which nothing other than that it is expressed and originates somewhere in the genome is known has no meaning or utility under 35 USC § 101. Assertions (h) and (i) are not convincing because the instant application gives no information about the location of any genomic sequence from which SEQ ID NO: 13 is derived. Thus, it is not even certain whether any promoter exists near SEQ ID NO: 13 to be isolated. In addition, the utility of any chromosome walk or chromosome landing in the absence of knowing the location of SEQ ID NO: 13 within the genome lack both specificity and substantial real world use. Throughout appellants' arguments, not one clear, specific, substantial, and credible utility is offered for SEQ ID NO: 13 or whatever SEQ ID NO: 13 may encode. Appellants assert that SEQ ID NO: 13 is analogous to a

Art Unit: 1631

microscope or gas chromatograph (*e.g.*, brief filed July 13, 2004, page 7) in the sense that it is a research tool. This analogy is weak because SEQ ID NO: 13 is not an apparatus at all, but is more akin to something that has been seen or detected with a research tool, than the research tool itself.

Appellants have asserted that claims 4-10 are separately patentable from claims 1,2, and 11-17 (see brief filed July 13, 2004, page 12, section (4)), but have offered no specific reasons that are not included in the arguments in connection with claims 1, 2, and 11-17 for such separate patentability. Thus, the examiner's arguments in connection with claims 1, 2, and 11-17 are incorporated here.

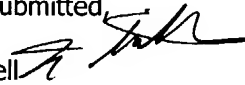
Art Unit: 1631

Rejection of claims 1, 2, and 4-17 under 35 USC § 112, first paragraph

Claims 1, 2, and 4-17 are rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection of the instant claims under 35 USC § 101 hereinabove is incorporated here. Appellants' arguments (brief filed July 13, 2004, paragraph bridging pages 12-13) are not convincing because in the absence of a patentable utility, the application does not teach one of skill in the art how to use the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

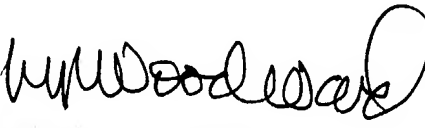
Respectfully submitted,

James Martinell 
Primary Examiner
Art Unit 1631

September 28, 2004

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